SECTION E: 510(k) SUMMARY

This summary of safety and effectiveness information is submitted in compliance with 21CFR807.92.

November 9, 2001

K013068

NOV 2 0 2001

Submitter Information:
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Contact Person: Margo Enright
Phone Number: 317-870-5610
FAX Number: 317-870-5608

Trade Name:
BioScanner Glucose Test Strips

Common Name: Glucose test system

Panel: Clinical Chemistry 75

Product Code: NBW

Device Classification: Class II

Intended Use
The BioScanner Glucose Test Strips are intended to be used to measure glucose by healthcare professionals in whole blood and by individuals with diabetes at home in fingerstick whole blood. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia and pancreatic islet cell tumors.

Device Description
Glucose in the whole blood sample reacts with glucose oxidase in the presence of peroxidase, 4-aminoantipyrine and a disubstituted aniline to produce a colored end product. The BioScanner reads the percent reflectance of the color produced and converts reflectance into glucose concentration.

Predicate Device Information

STATEMENT OF SUBSTANTIAL EQUIVALENCE
Polymer Technology Systems, Inc., intends to introduce into commercial distribution the BioScanner Glucose Test Strips for the quantitative determination of Glucose in human whole blood. The BioScanner Glucose Test Strips are substantially equivalent to the predicate device noted below.

Name: Accu-Chek Comfort Curve Test Strips
Device Company: Roche Diagnostics
510(k) Number: K 982002

Similarities and Differences (Predicate and BioScanner Beyond Glucose)

Similarities

- Both systems measure Glucose concentrations in blood.
- Both systems provide a result that correlates to the laboratory plasma glucose result.
- Both systems are calibrated with a glucose hexokinase laboratory method as the reference.
- Both reagents are similar in their composition in that both use a glucose oxidase reaction.
- Both systems require a lot specific memory chip for result calculation. Both systems contain the lot specific memory chip in the same package as the test strips.

Differences

The testing principle is different:

- The Accu-Chek testing principle is based on an amperometric method in which a small current produced in a chemical reaction is measured and converted to a glucose result.
- The BioScanner Glucose Test Strips use reflectance photometry to measure a color change that is converted to a glucose result.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 0 2001

Ms. Margo Enright
Manager of Clinical Affairs
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Re: k013068
Trade/Device Name: BioScanner Glucose Test Strips
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II, Class II
Product Code: NBW; CGA
Dated: August 28, 2001
Received: August 30, 2001

Dear Ms. Enright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

U.S. Food and Drug Administration Center for Devices and Radiological Health

NOV 2 0 2001

510(k) Number (if known): K013068

Device Name: BioScanner Glucose Test Strips

Indications for Use:

The BioScanner Glucose test strips are intended to be used to measure glucose by healthcare professionals in whole blood and by individuals with diabetes at home in fingerstick whole blood. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia and pancreatic islet cell tumors.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013068

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PA OF NEEDED)